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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,542	07/27/1999	DOUGLAS JOSEPH DOBROZSI	7247M	5652

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/361,542	DOBROZSI, DOUGLAS JOSEPH	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,38,41-43,46 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36,38,41-43,46 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and response dated 12-21-06 is acknowledged.

Claims 36, 38, 41-43, 46 and 48 are pending in the instant application.

Instant claims 36 and 43 have been amended to recite the limitation " 3% to 20%" colloidal particles and "wherein said oral, mucoretentive, aqueous liquid, pharmaceutical composition forms a gel-like mixture upon contact with a mucosal surface.
Claim 36 is directed to a method of administering an active agent and claim 43 is directed to a mucoretentive composition.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 36, 38, 41-43, 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,112,604 ('604) by itself.

'604 teaches oral, aqueous suspension formulations comprising a drug, a wetting agent, a hydrocolloid gum, colloidal silicon dioxide, antifoaming agent, citric acid, water and other components (col. 1, lines 40-57 and tables 1 and 2). With respect to the drug, '604 teach addition of anti-tussive, anti-inflammatory, bronchodilator etc (col. 3, lines 47-56), similar to those claimed in the instant. '604 teach the same amount of citric acid that falls within the instant claimed range (tables). With respect to the size and the amount of colloidal silicon particles claimed, instant claims 36 and 43 recite a range of

2% to 50% by weight of the composition. '604 teach upto 2% of colloidal silicon dioxide and thus meet the claimed percentage. Further, while '604 does not mention the particle size, the reference teaches "colloidal" silicon dioxide which by definition has a particle size in the range of nanometers (admitted on page 4, lines 29-36 of instant specification). Thus, absent evidence to the contrary, the particle size of the colloidal silicon dioxide of '604 meets the claimed range. '604 teach oral suspension that read on the claimed method of administering a medicament by swallowing the composition. '604 fail to specify the amount of water in the composition. However, both the examples of '604 recite ingredients that include water in the simple syrup preparation (col. 6, lines 14-20 and claim 1). Accordingly, absent unexpected advantage with the claimed high amounts of water, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include the appropriate amount of water to prepare an oral aqueous liquid composition comprising the claimed active agent, silicon dioxide and citric acid, without loosing the therapeutic efficiency of the drug as well as the stability afforded by silicon dioxide. With respect to the amount of silicon dioxide of instant claims 38 and 44, '604 teach upto 2% and not the claimed percentage. However, instant claims recite a wide range of "about 3% to about 50%" that includes very low and very high amounts, suggesting that the amount of silicon dioxide is not critical. Instant invention also fails to define what the term "about" stands for or what standard deviation constitutes "about 3%". Accordingly, in the absence of any unexpected advantage, one of an ordinary skill in the art would have been motivated to optimize the amount of silicon dioxide in the composition of '604 because '604 suggest that colloidal

silicon dioxide imparts stability to the suspension so as to remain stable in suspension for a long time.

Response to Arguments

Applicant's arguments filed 12-13-06 have been fully considered but they are not persuasive.

It is argued that the *prima facie obviousness* has not been established by the examiner in rejecting instant claims over the teaching of '604 (Beaurline). It is argued that '604 do not teach the claimed ranges of silicon dioxide (now amended to about 3% to about 50%). It is argued that claim 44, now amended is not obvious over '604 and with respect to claims 36 (and the dependent claims), the reference teaches no more than 2% colloidal silicon dioxide and hence teaches away from the claimed amounts. It is argued that the claimed amounts of silicon dioxide assists in achieving the particular mucoretentive properties of the invention whereas '604 is only interested in maintaining the active in suspension for prolonging storage and promoting uniform dosing. It is argued that instant claims now recite a "'mucoretentive'" composition, and clarify that <u>said oral, mucoretentive; aqueous liquid, pharmaceutical composition forms a gel-like mixture upon contact with a mucosal surface.</u> In this regard, applicants refer to page 8, line 24-28, page 6, line19-33, page 4, line 28-page 3, line 2, where the mucoretentive properties of the present composition are described with respect to the colloidal particles (including silicon dioxide). It is also argued '604 teach nothing with respect to mucoretentive compositions or mucoretentive properties, or any reason to make or

desire such compositions or properties and thus, one of skill in the art would not have been led by '604 to use the amounts of silicon dioxide used in the present invention. Furthermore, regardless of the use of the term "about', the presently claimed ranges are outside of those disclosed by Beaurline, and as explained above, and therefore, the Applicant's use of the term "about" would not equate to simply "optimizing" the silicon dioxide mounts of Beaurline. In addition, there is an unexpected, and un-taught, advantage of the present invention -that of mucoretentiveness, which Beaurline does not even contemplate.

The arguments are not persuasive because with respect to the composition claims, the only difference between instant claims and tat of '604 is the amount of silicon dioxide. Applicants argued that '604 teaches away from using above 2% but did not show where in '604 it is said that more than 2% should not be employed. In a composition claim, the motivation to add a particular ingredient need not be the same as that of the instant invention. Further, while '604 do not teach mucoretention, the property claimed as well as argued is of the entire composition (gel-like mixture). Further, instant description reveals that colloidal silicon dioxide forms a gel-like mixture over a range of percentages "about 2% to about 50%'. If according to applicants' disclosure 2% silica forms a gel, then the composition of '604 should also possess the same property (gel formation and mucoretention). Examiner notes that while claims recite gel-like mixture, applicants have not shown that the composition of '604 does not form such. With respect to the claimed method, examiner notes that the claimed method only recites " a method of administering an active agent" and further recites "wherein the

composition forms a gel-like mixture". Thus, the method claimed is only to administer a composition containing about 3% to about 50% colloidal silica and the formation of gel-like mixture is once again a property of the composition as long as the composition includes the claimed components. In this case, '604 do teach administering an active agent orally and hence is administered to the claimed stomach, esophagus or intestine. With respect to the claimed property of the forming a gel-like mixture, applicants once again have not shown that the composition of '604 does not form a gel-like mixture in comparison with the claimed composition that is commensurate with the scope of the claims. On the other hand, the composition of '604 does exhibit the property because according to the disclosure, the property is achieved or observed with colloidal silica in an amount ranging from about 2% to 50%. The term about 2% allows for a standard variation of at least 10%, in which case even 1.8% colloidal silicon dioxide should exhibit the claimed property. Therefore, the rejection has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
April 1, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER